AMENDMENT TO GLP TEST PROTOCOL

Amendment No.:	2
Effective Date:	July 27, 2016
Sponsor:	Rust-Oleum 11 Hawthorne Parkway Vernon Hills, IL 60061
Sponsor Representative:	Haley & Aldrich 455 E. Eisenhower Pkwy, Suite 210 Ann Arbor, MI 48408-3323
Test Facility:	Accuratus Lab Services 1285 Corporate Center Drive, Suite 110 Eagan, MN 55121
Protocol Title:	Fungicidal Germicidal Spray Method
Protocol Number:	RUO01040416.FGS
Project Number:	A20730

Modifications to Protocol:

Per Sponsor's request, the protocol is amended to cancel testing prior to the generation of valid data for Lot 1 dosed Book 600-075 and Lot 2 dosed Book 600-077. The neutralization confirmation controls for Lot 1 dosed Book 600-075 performed on 6/27/16 are valid.

Changes to the protocol are acceptable as noted.

Jamie Herzan
Study Director

7-27-16
Date

EXACT COPY
INITIALS JLH DATE 9-15-16

AMENDMENT TO GLP TEST PROTOCOL

Amendment No.:	1
Effective Date:	May 23, 2016
Sponsor:	Rust-Oleum 11 Hawthorne Parkway Vernon Hills, IL 60061
Sponsor Representative:	Haley & Aldrich 455 E. Eisenhower Pkwy, Suite 210 Ann Arbor, MI 48408-3323
Test Facility:	Accuratus Lab Services 1285 Corporate Center Drive, Suite 110 Eagan, MN 55121
Protocol Title:	Fungicidal Germicidal Spray Method
Protocol Number:	RUO01040416.FGS
Project Number:	A20730

Modifications to Protocol:

Due to contamination present in the purity and neutralization confirmation controls, the protocol is amended to cancel testing performed on May 16, 2016 prior to the generation of valid data.

Changes to the protocol are acceptable as noted.

Study Director

5-24-16
Date

EXACT COPY
INITIALS JLH DATE 9-15-16

(For Laboratory Use Only) CLH 4/22/16
Accuratus Lab Services Project# A20730
Test Substance Tracking # TS041516.RUO01
IQBA 4-18-16

ACCURATUS LAB SERVICES

PROTOCOL

Fungicidal Germicidal Spray Method

Test Organism(s):

Trichophyton mentagrophytes (ATCC 9533)

PROTOCOL NUMBER

RUO01040416.FGS

PREPARED FOR/SPONSOR

Rust-Oleum
11 Hawthorne Parkway
Vernon Hills, IL 60061

SPONSOR REPRESENTATIVE

Haley & Aldrich
455 E. Eisenhower Pkwy, Suite 210
Ann Arbor, MI 48108-3323

PREPARED BY/TESTING FACILITY

Accuratus Lab Services
1285 Corporate Center Drive, Suite 110
Eagan, MN 55121

DATE

April 4, 2016

EXACT COPY
INITIALS JLH DATE 9-15-16

Fungicidal Germicidal Spray Method

PURPOSE
The purpose of this study is to determine the effectiveness of the Sponsor's product as a disinfectant for hard surfaces following the AOAC Germicidal Spray Method. This method is in compliance with the requirements of and may be submitted to, one or more of the following agencies as indicated by the Sponsor: U.S. Environmental Protection Agency (EPA), Health Canada and Australian Therapeutic Goods Administration (TGA).

TEST SUBSTANCE CHARACTERIZATION
According to 40 CFR, Part 160, Subpart F [160.105] test substance characterization as to identity, strength, purity, solubility and composition, as applicable, shall be documented before its use in this study. The stability of the test substance shall be determined prior to or concurrently with this study. Pertinent information, which may affect the outcome of this study, shall be communicated in writing to the Study Director upon sample submission to Accuratus Lab Services. Accuratus Lab Services will append Sponsor-provided Certificates of Analysis (C of A) to this study report, if requested and supplied. Characterization and stability studies not performed following GLP regulations will be noted in the Good Laboratory Practice compliance statement.

SCHEDULING AND DISCLAIMER OF WARRANTY
Experimental start dates are generally scheduled on a first-come/first-serve basis once Accuratus Lab Services receives the Sponsor approved/completed protocol, signed fee schedule and corresponding test substance(s). Based on all required materials being received at this time, the proposed experimental start date is April 18, 2016. Verbal results may be given upon completion of the study with a written report to follow on the proposed completion date of May 16, 2016. To expedite scheduling, please be sure all required paperwork and test substance documentation is complete/accurate upon arrival at Accuratus Lab Services.

If a test must be repeated, or a portion of it, due to failure by Accuratus Lab Services to adhere to specified procedures, it will be repeated free of charge. If a test must be repeated, or a portion of it, due to failure of internal controls, it will be repeated free of charge. "Methods Development" fees shall be assessed, however, if the test substance and/or test system require modifications due to complexity and difficulty of testing.

If the Sponsor requests a repeat test, they will be charged for an additional test. Neither the name of Accuratus Lab Services nor any of its employees are to be used in advertising or other promotion without written consent from Accuratus Lab Services. The Sponsor is responsible for any rejection of the final report by the regulatory agencies concerning report format, pagination, etc. To prevent rejection, Sponsor should carefully review the Accuratus Lab Services final report and notify Accuratus Lab Services of any perceived deficiencies in these areas before submission of the report to the regulatory agency. Accuratus Lab Services will make reasonable changes deemed necessary by the Sponsor, without altering the technical data.

JUSTIFICATION FOR SELECTION OF THE TEST SYSTEM
Regulatory agencies require that a specific fungal claim for a test substance intended for use on hard surfaces be supported by appropriate scientific data demonstrating the efficacy of the test substance against the claimed fungi. This is accomplished by treating the target organism with the test substance under conditions which simulate as closely as possible, in the laboratory, the actual conditions under which the test substance is designed to be used. For products intended for use on hard surfaces (dry, inanimate environmental surfaces), a carrier method is used in the generation of the supporting data. The experimental design in this protocol meets these requirements.

TEST PRINCIPLE

A film of fungal cells dried on a surface of glass slide carriers is exposed to the test substance for a specified exposure time. After exposure, the carriers are transferred to vessels containing neutralizing subculture media and assayed for survivors. Appropriate culture purity, sterility, viability, neutralization confirmation and carrier population controls are performed. The current revision of Standard Operating Procedure CGT-0027 reflects the methods which shall be used in this study.

TEST METHOD

Test Organism	Designation #	Growth Medium	Incubation Parameters
Trichophyton mentagrophytes	9533	Sabouraud Dextrose Agar	25-30°C, aerobic

The test organism(s) to be used in this study was/were obtained from the American Type Culture Collection (ATCC), Manassas, VA.

Recovery Agar Medium: Glucose Agar

Carriers

Glass slides (25 mm x 25 mm, 25 mm x 75 mm, or 18 mm x 36 mm) unused and without visual defects will be utilized as the carrier for this assay. The carriers will be cleaned in 95% ethanol, rinsed in deionized water, and dried. The carriers will then be placed into a vessel and sterilized in an air oven for ≥2 hours at ≥180°C. Individual sterile plastic Petri dishes will be matted with two pieces of filter paper. One sterile glass slide will be transferred into each of the matted Petri dishes.

Preparation of Test Organism

A culture of *Trichophyton mentagrophytes* will be prepared by inoculating a sufficient number of agar plates using a stock culture and incubating at 25-30°C for 10-15 days. The mycelia will be removed from sufficient plates using a sterile device. The mycelia will be transferred to sterile glassware (e.g. an Erlenmeyer flask) containing glass beads and a ratio of 25 mL of sterile saline or saline/Triton Solution (0.85% Saline + 0.05 % Triton X-100) per 5 plates harvested. The culture will be agitated. Alternately, the mycelia may be added to a tissue grinder containing sterile saline or saline/Triton Solution and macerated. The culture will be filtered through sterile gauze to remove hyphal fragments. The conidial concentration will be estimated by counting in a hemacytometer and the culture may be adjusted as necessary. The inoculum must contain at least 1 x 10^7 condia/mL. The culture may be stored at 2-8°C for up to 4 weeks prior to use in testing. **Adjust the culture in 0.85% Saline + 0.05 % Triton X-100 (or 0.85% Saline, if necessary) to target 3-4 x 10^7 conidia/mL.**

An organic soil load may be added to the test culture per Sponsor's request. The test culture will be thoroughly mixed prior to use.

Contamination of Carriers

The glass slide carriers will each be inoculated with 0.01 mL (10 µL) of a prepared suspension (using a 4 mm loop or calibrated pipettor) uniformly spreading the suspension over the test surface (approximately 1 square inch) of the slide in a Petri dish. The dish will be covered immediately and the procedure repeated until all slides have been inoculated. The culture will be vortex mixed periodically during inoculation as necessary. The carriers will be dried for 30-40 minutes. *Organisms not specifically mentioned in the AOAC methodology may require modified drying conditions for the purpose of obtaining maximum survival following drying.* The actual drying conditions and observations noting that the carriers were visibly dry at the completion of drying will be clearly documented. Carriers shall be used in the test procedure within 2 hours of drying.

Drying Conditions: 35-37°C.

Preparation of Test Substance

The test substance(s) to be assayed will be used as directed by the Sponsor. For products requiring dilution, use ≥1.0 mL or ≥1.0 g of test substance and volumetric glassware when preparing the dilution unless otherwise specified by the Sponsor. If a dilution of the test substance is requested by the Sponsor, the diluted test substance(s) shall be used within three hours of preparation.

Exposure Conditions
Dried organism films will be exposed at room temperature, in an undisturbed horizontal position, to the amount of spray released under use conditions, for the time and at the distance specified by Sponsor. The actual temperature and humidity will be recorded. The carrier will be sprayed with the test substance within ±5 seconds of the exposure time for exposure times above 1 minute following a calibrated timer. The carrier will be sprayed with the test substance within ±3 seconds of the exposure time for exposure times of ≤1 minute. If the exposure conditions are compromised in any way for a given carrier, a new carrier may be treated in its place. If this cannot be done, the carrier will be marked and the compromised carrier will be identified in the raw data. If a marked carrier demonstrates a positive result, the carrier set may be invalidated and repeated by Sponsor request.

Test System Recovery
Following spray treatment, each treated carrier will be held at room temperature for the desired exposure time. At the end of the exposure time, the excess liquid will be drained off the carrier without touching the carrier to the Petri dish or filter paper. Each treated carrier is then transferred using sterile forceps and following identical staggered intervals to 20 mL aliquots of neutralizing subculture medium. Shake the vessel thoroughly. If necessary, carriers are transferred into individual secondary subcultures containing 20 mL of neutralizing subculture medium within approximately 25-60 minutes of the initial transfer. Shake the vessel thoroughly.

Incubation and Observation
All broth subcultures are incubated for 10 days at 25-30°C. The agar plate subcultures will be incubated for 66-76 hours at 25-30°C.

Additional incubation may be followed for the subculture plates if growth is hard to detect. Following incubation, the subcultures will be visually examined for growth. If necessary, the subcultures may be placed at 2-8°C for up to three days prior to examination. Representative subculture tubes showing growth will be subcultured, stained and/or biochemically assayed to confirm or rule out the presence of the test organism. If growth cannot be determined visually, appropriate test and/or control subcultures may be streaked to agar to determine the presence or absence of growth.

STUDY CONTROLS

Purity Control
A "streak plate for isolation" will be performed on each organism culture and following incubation examined in order to confirm the presence of a pure culture. The acceptance criterion for this study control is a pure culture demonstrating colony morphology typical of the test organism.

Organic Soil Sterility Control
Prior to or concurrent with testing and if applicable, the serum used for the organic soil load will be cultured, incubated, and visually examined for lack of growth. The acceptance criterion for this study control is lack of growth.

Carrier Sterility Control
Prior to or concurrent with testing, a representative uninoculated carrier will be added to an appropriate subculture medium. The subculture medium containing the carrier will be incubated and examined for growth. The acceptance criterion for this study control is lack of growth.

Neutralizing Subculture Medium Sterility Control
Prior to or concurrent with testing, a representative sample of uninoculated neutralizing subculture medium will be incubated and visually examined. The acceptance criterion for this study control is lack of growth.

Viability Control
One representative inoculated carrier will be added to a vessel containing each type of subculture medium. If secondary subcultures are performed using a different media type, one carrier will be placed in the primary subculture medium and one carrier will be placed in the secondary subculture medium. The vessels containing each carrier will be incubated and visually examined for growth. The acceptance criterion for this study control is growth in the subculture media.

Neutralization Confirmation Control
The neutralization of the test substance will be confirmed prior to testing or concurrent with testing by exposing at least one sterile carrier to the test substance and transferring the carrier to primary subcultures containing 20 mL of neutralizing subculture medium as in the test. If performed in the test procedure, each carrier will then be transferred from primary subcultures into individual secondary subcultures beginning approximately 25-60 minutes following the primary transfer. The subcultures (primary and secondary as applicable) will be inoculated with a target of 10-100 colony forming units (CFU) of each test organism, incubated under test conditions and visually examined for the presence of growth. This control will be performed with multiple replicates using different dilutions of the test organism. A standardized spread plate procedure will be run concurrently in order to enumerate the number of CFU actually added per tube. NOTE: Only the most concentrated test substance dilution and/or shortest exposure time needs to be evaluated in this control.

The acceptance criterion for this study control is growth in the final subculture broth, minimally, following inoculation with ≤100 CFU per tube. If all the organism dilution(s) used in this control fail to provide adequate numbers (10-100 CFU) which coincides in a failure to meet the acceptance criterion for this study control, the control may be repeated in its entirety.

Carrier Population Control
Two sets of three inoculated carriers (one set prior to testing and one set following treatment) for each organism carrier set will be assayed. Each inoculated carrier will be individually subcultured into a vessel containing 20 mL of neutralizing subculture medium and immediately vortex mixed for 120±5 seconds. Following mixing, the contents of the three subcultured carriers will be pooled (60 mL). Appropriate serial ten-fold dilutions will be prepared and the duplicate 0.1 mL aliquots spread plated on agar plate medium, and incubated. If serial dilutions are not performed and plated immediately following mixing, the vessels may be refrigerated at 2-8°C for up to 2 hours prior to dilution. Following incubation, the resulting colonies will be enumerated. The individual CFU per carrier set results will be calculated, and the Log_{10} value of each carrier set determined. The average Log_{10} value per organism will be calculated. The acceptance criterion for this study control is a minimum average Log_{10} value of 4.0.

PROCEDURE FOR IDENTIFICATION OF THE TEST SYSTEM
Accuratus Lab Services maintains Standard Operating Procedures (SOPs) relative to efficacy testing studies. Efficacy testing is performed in strict adherence to these SOPs which have been constructed to cover all aspects of the work including, but not limited to, receipt, log-in, and tracking of biological reagents including test organism strains for purposes of identification, receipt and use of chemical reagents. These procedures are designed to document each step of efficacy testing studies. Appropriate references to medium, batch number, etc. are documented in the raw data collected during the course of each study.

Additionally, each efficacy test is assigned a unique Project Number when the protocol for the study is initiated by the Study Director. This number is used for identification of the test subcultures, etc. during the course of the test. Test subcultures are also labeled with reference to the test organism, experimental start date, and test product. Microscopic and/or macroscopic evaluations of positive subcultures are performed in order to confirm the identity of the test organism. These measures are designed to document the identity of the test system.

METHOD FOR CONTROL OF BIAS: NA

STUDY ACCEPTANCE CRITERIA

Test Substance Performance Criteria
The efficacy performance requirements for label claims state that the test substance must kill the microorganism on 10 out of the 10 inoculated carriers.

Control Acceptance Criteria
The study controls must perform according to the criteria detailed in the study controls description section. If any of the control acceptance criteria are not met, the test may be repeated under the current protocol number. If the population control exceeds an average $\log_{10}$ value of 5.0 for *Trichophyton mentagrophytes*, and the test substance does not meet the performance criteria, the Sponsor may invalidate the study and repeat testing.

Any positive test carriers confirmed as a contaminant will be reported. Any test carrier set that demonstrates a number of contaminated tubes that contributes to results that exceed the product performance/success criteria may be invalidated per Sponsor's request and may be re-tested.

If any portion of the protocol is executed incorrectly warranting repeat testing, the test may be repeated under the current protocol number. If the population control falls to meet the minimum requirement or if the neutralization control acceptance criteria is not met and the study fails to meet the efficacy requirements, repeat testing is not required.

REPORT
The report will include, but not be limited to, identification of the sample, date received, initiation and completion dates, identification of the fungal strains used, description of media and reagents, description of the methods employed, tabulated results and conclusion as it relates to the purpose of the test, and all other items required by 40 CFR Part 160.185.

PROTOCOL CHANGES
If it becomes necessary to make changes in the approved protocol, the revision and reasons for changes will be documented, reported to the Sponsor and will become a part of the permanent file for that study. Similarly, the Sponsor will be notified as soon as possible whenever an event occurs that may have an effect on the validity of the study.

Standard operating procedures used in this study will be the correct effective revision at the time of the work. Any minor changes to SOPs (for this study) or methods used will be documented in the raw data and approved by the Study Director.

TEST SUBSTANCE RETENTION
It is the responsibility of the Sponsor to retain a sample of the test substance. All unused test substance will be discarded following study completion unless otherwise indicated by Sponsor.

RECORD RETENTION

Study Specific Documents

All of the original raw data developed exclusively for this study shall be archived at Accuratus Lab Services for a minimum of five years for GLP studies or a minimum of six months for all other studies following the study completion date. After this time, the Sponsor (or the Sponsor Representative, if applicable) will be contacted to determine the final disposition. These original data include, but are not limited to, the following:

1. All handwritten raw data for control and test substances including, but not limited to, notebooks, data forms and calculations.
2. Any protocol amendments/deviation notifications.
3. All measured data used in formulating the final report.
4. Memoranda, specifications, and other study specific correspondence relating to interpretation and evaluation of data, other than those documents contained in the final study report.
5. Original signed protocol.
6. Certified copy of final study report.
7. Study-specific SOP deviations made during the study.

Facility Specific Documents

The following records shall also be archived at Accuratus Lab Services. These documents include, but are not limited to, the following:

1. SOPs which pertain to the study conducted.
2. Non study-specific SOP deviations made during the course of this study which may affect the results obtained during this study.
3. Methods which were used or referenced in the study conducted.
4. QA reports for each QA inspection with comments.
5. Facility Records: Temperature Logs (ambient, incubator, etc.), Instrument Logs, Calibration and Maintenance Records.
6. Current curriculum vitae, training records, and job descriptions for all personnel involved in the study.

REFERENCES

1. Association of Official Analytical Chemists (AOAC) Official Method 961.02, Germicidal Spray Products as Disinfectants. In Official Methods of Analysis of the AOAC, 2012 Edition.
2. Association of Official Analytical Chemists (AOAC) Official Method 960.09, Germicidal and Detergent Sanitizing Action of Disinfectants [Preparation of Synthetic Hard Water]. In Official Methods of Analysis of the AOAC, 2013 Edition.
3. U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Product Performance Test Guidelines, OCSPP 810.2000: General Considerations for Uses of Antimicrobial Agents, September 4, 2012.
4. U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Product Performance Test Guidelines, OCSPP 810.2200: Disinfectants for Use on Hard Surfaces- Efficacy Data Recommendations, September 4, 2012.
5. Health Canada, January, 2014. Guidance Document – Safety and Efficacy Requirements for Hard Surface Disinfectant Drugs.
6. Health Canada, January, 2014. Guidance Document - Disinfectant Drugs.
7. Australian Therapeutic Goods Administration (TGA), February 1998. Guidelines for the Evaluation of Sterilants and Disinfectants.
8. Australian Therapeutic Goods Administration (TGA), February 1998. Therapeutic Goods Order No. 54: Standard for Disinfectants and Sterilants.
9. Australian Therapeutic Goods Administration (TGA), March 1997. Therapeutic Goods Order No. 54A: Amendment to the Standard for Disinfectants and Sterilants (TGO 54).

DATA ANALYSIS

Calculations

Determine the CFU/Carrier set in the Carrier Population Control using all average counts between 0-300 CFU as follows:

$$\text{CFU/carrier} = \frac{[(\text{avg. CFU for } 10^{-x}) + (\text{avg. CFU for } 10^{-y}) + (\text{avg. CFU for } 10^{-z})] \times (\text{Volume of neutralizer})}{[10^{-x} + 10^{-y} + 10^{-z}] \times (\text{Volume plated}) \times (\#\text{ of carriers per set})}$$

where 10^{-x}, 10^{-y}, and 10^{-z} are example dilutions that may be used

$$\text{Average Log}_{10}\text{ Carrier Population Control} = \frac{\text{Log}_{10}X_1 + \text{Log}_{10}X_2 + \ldots \text{Log}_{10}X_N}{N}$$

Where: X equals CFU/carrier set
N equals number of control carrier sets

Statistical Analysis: None used

STUDY INFORMATION

(All blank sections are completed by the Sponsor or Sponsor Representative as linked to their signature, unless otherwise noted.)

Test Substance (Name and Batch Number) exactly as it should appear on final report:
(1) Mold Killing Primer Aerosol - Lot 1 dosed Book 600-075 (3) Aerosol Paint Control - Blank Book 600-075
(2) Mold Killing Primer Aerosol - Lot 2 dosed Book 600-077

Testing at the lower certified limit (LCL) is required for registration with Health Canada, no aged batch is necessary.

Product Description:
☐ Quaternary ammonia ☐ Peracetic acid ☐ Iodophor ☐ Peroxide
☐ Sodium hypochlorite ☒ Other 3-Iodo 2-propynyl butyl carbamate (IPBC)

Approximate Test Substance Active Concentration (upon submission to Accuratus Lab Services):
0.135 %
(This value is used for neutralization planning only. This value is not intended to represent characterization values.)

Neutralization/Subculture Broth: ☐ _____
(NOTE: All broth must also serve as an appropriate growth medium for the test organism)
☒ Accuratus Lab Services' Discretion. By checking, the Sponsor authorizes Accuratus Lab Services, at their discretion, to perform neutralization confirmation assays at the Sponsor's expense prior to testing to determine the most appropriate neutralizer. (See Fee Schedule).

Storage Conditions
☒ Room Temperature
☐ 2-8°C
☐ Other _____

Hazards
☐ None known: Use Standard Precautions
(1) ☒ Material Safety Data Sheet, Attached for each product
☐ As Follows: _____

Product Preparation
☒ No dilution required, Use as received (RTU)
☐ *Dilution(s) to be tested:
_____ defined as _____ + _____
(example: 1 oz/gallon) (amount of test substance) (amount of diluent)
☐ Deionized Water (Filter or Autoclave Sterilized)
☐ Tap Water (Filter or Autoclave Sterilized) - All tap water is softened; the water hardness for the batch of tap water used will be determined and reported.
☐ AOAC Synthetic Hard Water: _____PPM
☒ Other Shake well before use

***Note: An equivalent dilution may be made unless otherwise requested by the Sponsor.**

Test Organism(s): ☑ *Trichophyton mentagrophytes* (ATCC 9533)

Carrier Number: 10 per batch

Spraying Time or # of Sprays: one spray
(1) ~~One~~ or until thoroughly wet

Approximate Spraying Distance: ☐ 6-8 inches (visually estimated) or 8-12"

Exposure Time: 10 Minutes **Exposure Temperature:** Room temperature (18-25 °C)

Organic Soil Load:
☒ Minimum 5% Organic Soil Load (Fetal Bovine Serum)
☐ No Organic Soil Load Required
☐ Other _____

(1) Added per email. JLH 4-19-16

SPRAY BOTTLES USED IN TESTING

To ensure expected levels of product are delivered, it is recommended that the Sponsor provide the spray bottles used in testing. Please indicate the desired source of the sprayer bottles used in testing:

☒ Sprayer(s) and bottle(s) are provided by the Sponsor
☐ General purpose spray bottle(s) are to be provided by Accuratus Lab Services
☐ The spray nozzle(s) are provided by the Sponsor and general purpose bottle(s) will be provided by Accuratus Lab Services

TEST SUBSTANCE SHIPMENT STATUS

(This section is for informational purposes only.)

☐ Test Substance is already present at Accuratus Lab Services.
☑ Test Substance has been or will be shipped to Accuratus Lab Services.
Date of expected receipt at Accuratus Lab Services: : April 11, 2016
☐ Test Substance to be hand-delivered (must arrive by noon at least one day prior to testing or other arrangements made with the Study director).

COMPLIANCE

Study to be performed under EPA Good Laboratory Practice regulations (40 CFR Part 160) and in accordance to standard operating procedures.
☑ Yes
☐ No (Non-GLP or Development Study)

REGULATORY AGENCY(S) THAT MAY REVIEW DATA

☑ U.S. EPA
☐ Health Canada
☐ Therapeutic Goods Administration (Australian TGA)

PROTOCOL MODIFICATIONS

☐ Approved without modification
☑ Approved with modification
All carriers sprayed with the test material will be scraped with a sterile device, following secondary neutralization, to ensure the paint is integrated in the system and aid in organism recovery. In addition to the standard 2 lot test, one lot of control material will be tested using 3 test carriers. The results of the control lot will be for informational purposes only and will have no acceptance criteria.

PROTOCOL ATTACHMENTS

Supplemental Information Form Attached - ☐ Yes ☑ No

TEST SUBSTANCE CHARACTERIZATION & STABILITY TESTING
[Verification required per 40 CFR Part 160 Subpart B (160.31(d))].

☐ Characterization/Stability testing is not required (For Non-GLP or Development testing only)

OR

Physical and Chemical Characterization (Identity, purity, strength, solubility, as applicable) of the test lots

☑ **Physical & Chemical Characterization has been or will be completed prior to efficacy testing.**

GLP compliance status of physical & chemical characterization testing:
☑ Testing was or will be performed following 40 CFR Part 160 GLP regulations
☐ Characterization has not been or will not be performed following GLP regulations

Check and complete the following that apply:
☐ A Certificate of Analysis (C of A) may be provided for each lot of test substance. If provided, the C of A will be appended to the report.
☐ Testing has been or will be conducted at Accuratus Lab Services under protocol or study #: _____
☐ Test has been or will be conducted by another facility under protocol or study #: _____

☐ **Physical & Chemical Characterization was not or will not be performed prior to efficacy testing.**

Stability Testing of the formulation

☒ **Stability testing has been or will be completed prior to or concurrent with efficacy testing.**

GLP compliance status of stability testing:
(GLP compliance is required by 40 CFR Part 160)
① ☒ Testing was or will be performed following 40 CFR Part 160 GLP regulations
☐ Stability testing has not been or will not be performed following GLP regulations

Check and complete the following that apply:
☐ Testing has been or will be conducted at Accuratus Lab Services under protocol or study #: _____
☒ Test has been or will be conducted by another facility under protocol or study #: Product Safety Labs #42075 (dated 1/5/2016)

☐ **Stability testing was not or will not be performed prior to or concurrent with efficacy testing.**

If test substance characterization or stability testing information is not provided or is not performed following GLP regulations, this will be indicated in the GLP compliance statement of the final report.

①Added per email. JLH 4-19-16

APPROVAL SIGNATURES

SPONSOR:

NAME: Ms. Maryann Sanders TITLE: Agent

SIGNATURE: [signature] DATE: 4/15/2016

PHONE: ~~(248) 682 - 9920~~ 378-3957 FAX: (734) 877 - 8425 EMAIL: msanders@HaleyAldrich.com

For confidentiality purposes, study information will be released only to the sponsor/representative signing the protocol (above) unless other individuals are specifically authorized in writing to receive study information.

Other individuals authorized to receive information regarding this study: ☐ See Attached

Accuratus Lab Services:

NAME: Jamie Herzan
Study Director

SIGNATURE: Jamie Herzan DATE: 4-22-16
Study Director